

CLINICAL PHARMACOLOGY

Microbiology:

Gentamicin sulfate is active *in vitro* against many strains of the following microorganisms:

Staphylococcus aureus, *Staphylococcus epidermidis*,
Streptococcus pyogenes, *Streptococcus pneumoniae*,
Enterobacter aerogenes, *Escherichia coli*, *Haemophilus*
influenzae, *Klebsiella pneumoniae*, *Neisseria gonorrhoeae*,
Pseudomonas aeruginosa, and *Serratia marcescens*.

INDICATIONS AND USAGE

Gentamicin sulfate ophthalmic solution/ointment is indicated in the topical treatment of ocular bacterial infections including conjunctivitis, keratitis, keratoconjunctivitis, corneal ulcers, blepharitis, blepharoconjunctivitis, acute meibomianitis, and dacryocystitis, caused by susceptible strains of the following microorganisms:

Staphylococcus aureus, *Staphylococcus epidermidis*,
Streptococcus pyogenes, *Streptococcus pneumoniae*,
Enterobacter aerogenes, *Escherichia coli*, *Haemophilus*
influenzae, *Klebsiella pneumoniae*, *Neisseria gonorrhoeae*,
Pseudomonas aeruginosa, and *Serratia marcescens*.

CONTRAINDICATIONS

Gentamicin sulfate ophthalmic solution/ointment is contraindicated in patients with known hypersensitivity to any of the components.

WARNINGS

NOT FOR INJECTION INTO THE EYE.

Gentamicin sulfate ophthalmic solution/ointment is not for injection. It should never be injected subconjunctivally, nor should it be directly introduced into the anterior chamber of the eye.

PRECAUTIONS

General:

Prolonged use of topical antibiotics may give rise to overgrowth of nonsusceptible organisms including fungi. Bacterial resistance to gentamicin may also develop. If purulent discharge, inflammation or pain becomes aggravated, the patient should discontinue use of the medication and consult a physician.

If irritation or hypersensitivity to any component of the drug develops, the patient should discontinue use of this preparation and appropriate therapy should be instituted.

Ophthalmic ointments may retard corneal healing.

Information for patients:

To avoid contamination, do not touch tip of container to the eye, eyelid or any surface.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

There are no published carcinogenicity or impairment of fertility studies on gentamicin. Aminoglycoside antibiotics have been found to be non-mutagenic.

Pregnancy:

Pregnancy Category C. Gentamicin has been shown to depress body weights, kidney weights and median glomerular counts in newborn rats when administered systemically to pregnant rats in daily doses approximately 500 times the maximum recommended ophthalmic human dose. There are no adequate and well-controlled studies in pregnant women. Gentamicin should be used during pregnancy only

Gentamicin Sulfate Ophthalmic Solution
Gentamicin Sulfate Ophthalmic Ointment

Labeling Guidance
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if the potential benefit justifies the potential risk to the fetus.

ADVERSE REACTIONS

Bacterial and fungal corneal ulcers have developed during treatment with gentamicin ophthalmic preparations.

The most frequently reported adverse reactions are ocular burning and irritation upon drug instillation, non-specific conjunctivitis, conjunctival epithelial defects and conjunctival hyperemia.

Other adverse reactions which have occurred rarely are allergic reactions, thrombocytopenic purpura and hallucinations.

DOSAGE AND ADMINISTRATION

Ophthalmic Solution:

Instill one or two drops into the affected eye(s) every four hours. In severe infections, dosage may be increased to as much as two drops every hour.

Ophthalmic Ointment:

Apply a small amount (approximately 1/2 inch ribbon) of ointment to the affected eye(s) two or three times a day.

HOW SUPPLIED

- Established name
- Strength of the dosage form
- Packaging
- Special handling and storage conditions

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